



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Jasmin Jackson, Risk Manager

From: Virna Stillwaugh, Ph.D., Entomologist

A handwritten signature in black ink, appearing to read "Stillwaugh", is written over the "From:" line.

Secondary Review: Jennifer Saunders, Ph.D., Senior Biologist

Handwritten initials "JS" in black ink are written to the right of the "Secondary Review:" line.

Date: 11/19/2020

Subject: REBUTTAL TO DP# 458797, DATED 10/08/2020

THIS REBUTTAL REVIEW DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 459933

Decision no.: 567628

Submission no: 1059787

Action code: R340.30

Product Name: Thermacell Radius Zone Mosquito Repellent VI

EPA Reg. No or File Symbol: 71910-11

Formulation Type: Spatial Repellent

Ingredients statement from the label with PC codes included:

Metofluthrin 5.5%

PC: 109709

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 sq ft or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate): 1 device will create a 20 ft protection zone. Place devices 20 ft apart from each other.

Use Patterns: Battery-powered metofluthrin emitting device product. For outdoor use only.

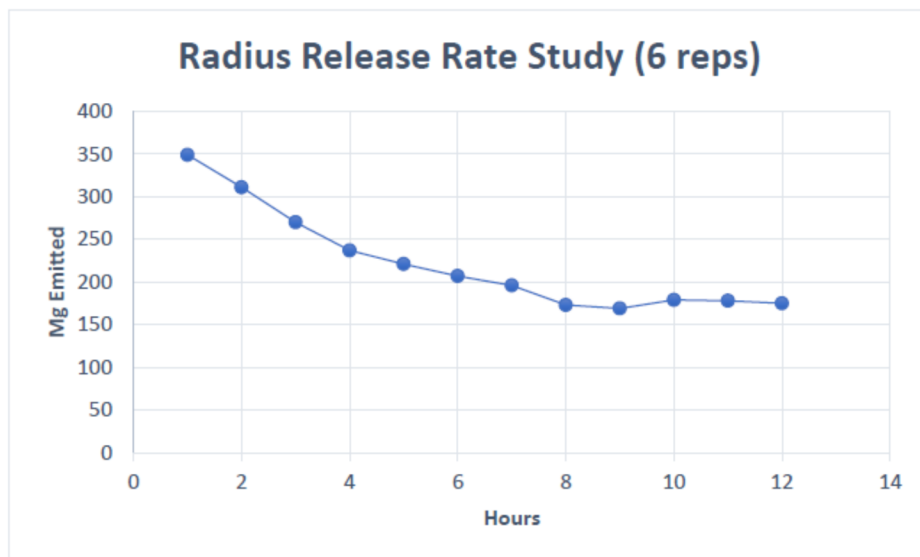
I. Action Requested: The registrant requested review of a rebuttal argument (no MRID, email submission) in response to the previous review (DP 458797), dated 10/08/2020.

II. Background: The original DER (MRID 51176601) recommended to add a 2-hour pre-burning time to the label, because that is how the product was tested. For the original submission, the registrant submitted data to support the increase of the product area coverage from 10 ft to 20 ft.

III. Rebuttal Summary:

Rebuttal Point #1. *We have adopted a practice of conducting a two-hour pre-burn before initiating efficacy studies in order to ensure that the efficacy data will be representative of the majority of the life of the product refill. The*

early-use emissions for these refills is typically a little higher than that of the remainder of the refill life. The efficacy in the early hours should be at least as good as later hours, but are not consistent with later release rates. The chart below provides an illustration of this.



Radius liquid release was measured from a 12-hour release test with a 5.5% metofluthrin Radius liquid (ECS-G-233) filled in 12-hour Radius refills using Radius units EID-19-018-1A/B/C/D/E/F. Lab book reference: ECS-48-035.

Agency Response to Rebuttal Point #1. Thank you for providing this information. The chart submitted is only showing release rates of the device over time. The chart shows that the initial release is higher than later times, and it does not stabilize until 8 hours after burning. There is no efficacy data submitted to see how efficacy changes over time. While efficacy data may have illustrated the rationale for the 2-hour pre-burn better, the Agency would not have reviewed this new data, as new data are not typically reviewed with a rebuttal submission. The outstanding issue is that the product was tested using a 2- hour pre-burn somewhere else, and the efficacy testing was performed after that period. Products should be tested in the same manner that they are going to be used.

Rebuttal Point #2. *This procedure using a pre-burn has been used in previous EPA submitted and accepted Thermacell efficacy studies.*

Agency Response to Rebuttal Point #2. Thank you for the clarification. The Agency acknowledges that the currently approved label does not have a two hour burn period. This current submission is only intended to support an increase of the product area coverage (from 10 ft to 20 ft). There are no additional pests or efficacy claims, and therefore in this case the current approved language is acceptable. However, future studies should include testing according to proposed labeling use directions.

IV. EXECUTIVE DATA SUMMARY:

The status of MRID 51176601 remains “acceptable.” The Agency is accepting not to include the 2-hour initial pre-burn time in the label, because there is already a pre-approved label for this product without this language based on data from a similar study design. The current submission is only intended to support an increase of the product area coverage (from 10 ft to 20 ft). There are no additional pests or efficacy claims, and therefore in this case the current approved language is acceptable. However, future studies should include testing according to proposed labeling use directions.

V. LABEL RECOMMENDATIONS: Refer to the efficacy review dated 10/08/2020 (DP# 458797), except for the recommendation of adding a 2-hour initial burn off time to the label.